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U.S. Appln. Ser. No.: 09/410,484
Attorney Docket No. NATNUT-03972

REMARKS

Claims 1-3, 7, and 9 are pending in the present application. Applicants appreciatively acknowledge the Examiner's withdrawal of the indefiniteness rejection of Claim 9 in response to their July 20, 2001, communication. However, the Examiner has maintained her rejection of each of the pending Claims as allegedly being obvious under Langer (Clin. and Exper. Hypertension, 17(7):1127-1144 (1995)) and Udell (Information About Conjugated Linoleic Acid, published by Soft Gel Technologies Incorporated).

Applicants believe that the remarks presented herein overcome all of the Examiner's remaining rejections.

**Three Requirements Must be Met to Establish a *prima facie* Case of
Obviousness by a Preponderance of the Evidence**

To establish a finding of *prima facie* obviousness, the Examiner must show by a "preponderance of the evidence" that the claimed invention is obvious. (MPEP §2142). "The legal standard of 'a preponderance of the evidence' requires . . . the examiner provide evidence which as a whole shows that the legal determination sought to be proved (*i.e.*, the reference teachings establish a *prima facie* case of obviousness) is more probable than not." (MPEP §2142; emphasis added).

The Examiner is well aware that there are three requirements that **must** be satisfied in order to meet the evidentiary burdens requisite to establishing a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings. A recent Federal Circuit decision articulates this point. In *C.R. Bard, Inc. v. M3 Sys. Inc.*, the Federal Circuit held that providing a suggestion, teaching or motivation to combine the prior art references is "**an essential evidentiary component** of an obviousness holding." (*C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998); emphasis added). Regardless of the source of evidence, the Examiner's showing "must be clear and particular, and broad **conclusory** statements about the teaching of multiple references, standing alone, are not 'evidence'." (*In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999); emphasis added). Thus, the

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Examiner's burden is to present clear and particular evidence that supports the combination or modification of the cited references. Importantly, since the Examiner is **NOT** one skilled in the art (under the law), the Examiner's opinions as to what one skilled in the art might believe do not constitute evidence. (*In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993) ("The examiner's assumptions do not constitute the disclosure of the prior art."); *See also*, MPEP §2144.03). The Examiner's knowledge of relevant facts which are used to make the rejection only constitute evidence if entered into the record by affidavit. (*See*, 37 CFR 1.107(b); MPEP §2144.03).

Second, at the time of invention there must have existed a reasonable expectation of success should the proposed combination or modification had been carried out. (MPEP §2143.02).

Third, the references must teach or suggest every claim element. (*In re Royka*, 490 F.2d 981 (CCPA 1974); *See also*, MPEP §2143.03). This evaluation requires "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." (*In re Wilson*, 424 F.2d 1382,1385 (CCPA 1970)).

Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness and, without more, entitles the Applicants to allowance of the claims at issue. (*See e.g.*, *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321 (Fed. Cir. 1990)). Applicants submit that even if the references are combined (wrongfully) they do not teach every claim element. In addressing this rejection, Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.¹

1. The Examiner has Failed to Establish a *Prima Facie* Case of Obviousness

Claims 1-3, 7, and 9 are rejected under 35 U.S.C. §103(a), as allegedly being obvious under Langer and Udell. Applicants must respectfully disagree. In addressing this rejection,

¹ §MPEP 2143.03.

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Applicants focus on the independent claims since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent therefrom.²

Applicants respectfully submit that the Examiner has apparently failed to accord the due weight to the Declaration of Drs. Ip and Dong submitted with the Applicants' response to the July 20, 2001, Final Office Action in the parent application. (See, Appendix 2). In their October 15, 2001, response the Applicants respectfully directed the Examiner's attention the Declaration of Drs. Hong and Ip. In their Declaration, Drs. Hong and Ip demonstrated that the effect of CLA is NOT due to weight loss as hypothesized by the Examiner, but instead is likely due to the action of CLA on genes known to be involved in hypertension, including those encoding angiotensin, angiotensin converting enzyme, angiotensin I receptor, angiotensin II receptor, endothelin converting enzyme, and ET-B endothelin receptor. Furthermore, the Declarant's interpretation of the Langer and Udell references is consistent with that advanced previously, namely that a person of ordinary skill in the art would not believe upon reading the cited references that the body composition altering effects of CLA would have any relation to the treatment of hypertension.

In response to the Applicants' Declaration, the Examiner's argues that the Declaration "merely demonstrates that CLA has an effect on compounds and receptors concerned with vasoconstriction. Applicants have not shown that weight loss is not a mediating factor." (Final Office Action, p. 4). The Examiner's single conclusory statement regarding the Declaration of Drs. Hong and Ip does not, however, address, let alone provide a sufficient evidentiary basis rebutting the assertions of fact contained within the Declaration.

Applicants respectfully remind the Examiner that she MUST consider and weigh all of the arguments and evidence presented by Applicants in each communication. The MPEP states that:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. . . . In re Beattie, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . Office personnel should avoid giving evidence no weight, except in rare circumstances. Id. See also In re Alton, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).

² §MPEP 2143.03.

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A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.

(MPEP § 2144.08; emphasis added). Indeed, the Applicants' right to have the Examiner consider all of the evidence of non-obviousness anew is especially true with regard to any fact based Rule 132 Declarations that the Applicants have submitted. The Applicants' right to have their Rule 132 Declarations considered and responded to by the Examiner is well settled law. For instance, in the case of *In re Reuter*, the C.C.P.A. held that "[a]s long as there is a question of obviousness, no matter how trivial that question may seem, we think appellants have the right to have considered the Rule 132 affidavit." (*In re Orfeo*, 169 USPQ 487 (C.C.P.A. 1971); *See also, In re Reuter*, 210 USPQ 249 (C.C.P.A. 1981) (holding "[s]tatements [contained in a Declaration submitted by the Applicant] are probative and at a minimum, constitute expert opinion evidence.")).

As it stands, the Examiner has failed to address the research of Drs. Hong and Ip presented in the October 15, 2001, Rule 132 Declaration. In particular, Drs. Hong and Ip (two researchers expert in the field in view of their respective curriculum vita) submitted that the Examiner's basis for making the cited combination was scientifically unsound in view of their experimental results discussed in paragraphs 4-6 and their knowledge of the field. Furthermore, as shown above, the Examiner's disputatious response is conspicuously lacking any evidentiary basis. Applicants remind the Examiner that by law she is not one skilled in the art and that her assumptions do not constitute the disclosure of the prior art." (*In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993). Thus, the Examiner has failed to establish a valid *prima facie* case of obviousness over the presently claimed invention.

Furthermore, while Applicants again submit that Examiner has failed to establish a valid *prima facie* case of obviousness over the presently claimed invention, assuming *arguendo* that the Examiner has established a *prima facie* case of obviousness, Applicants


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have more than sufficiently rebutted the Examiner's case by presenting evidence of non-obviousness in the Hong and Ip Declaration. Accordingly, Applicants submit that even if the Examiner had established a *prima facie* case of obviousness (Applicants submit that she did not), it has been rebutted by the fact based Declaration of Drs. Hong and Ip. Thus, the burden of establishing the *prima facie* obviousness falls back upon the Examiner.

For the reasons stated above, Applicants submit that the Examiner has not properly considered their July 20, 2001, fact based Rule 132 Declaration which overcomes the Examiner's remaining obviousness rejection and places the presently claimed invention in condition for allowance.

Conclusion

All grounds of rejection and objection of the Office Action of July 23, 2001 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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APPENDIX 1

1. A method of treating hypertension in humans comprising:
 - a) providing a subject and a composition comprising a safe and effective amount conjugated linoleic acid; and
 - b) administering said conjugated linoleic acid composition to said subject under conditions such that blood pressure of said subjects is reduced.
2. The method of Claim 1 wherein the conjugated linoleic acid composition is a mixture of octadecadienoic acid isomers selected from the group of cis-9, trans-11; cis-9, cis-11; trans-9, cis-11; trans-9, trans-11; cis-10, cis-12; cis-10, trans-12; trans-10, cis-12; trans-10, trans-12 octadecadienoic acid.
3. The method of Claim 1 wherein the conjugated linoleic acid composition consists essentially of octadecadienoic acid isomers selected from 9,11 octadecadienoic acid, 10,12 octadecadienoic acid, and mixtures thereof.
7. The method of Claim 1 wherein the conjugated linoleic acid is administered orally.
9. The method of Claim 1 wherein said safe and effective amount of conjugated linoleic acid is about 0.1 grams to 20 grams.

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APPENDIX 2